



INSPECTION REPORT

MSMITH
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ALZA CORPORATION

1900 CHARLESTON ROAD
P.O. BOX 7210
MOUNTAIN VIEW, CA 94043

Customer ID: 1171

Certificate: 93-R-0056

Site: 001

ALZA CORPORATION

Inspection

Type: ROUTINE INSPECTION

Date: OCT-03-2002

2.31 (d) (2)

2.31 (d) (4)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(2) IACUC review of activities involving animals. No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum.

Several protocols reviewed had the investigator/study director and others directly involved with the study as approving officials on the protocol. Protocol BIO-01-B002-3400 had 3 signatures on the approval page, (1) the study director, (2) biologist, directly involved with the study and the (3) an IACUC member. I was told that all GLP protocols are required to have the investigator/research director approve and sign their protocols.

Individuals personally involved in research activities being the majority of approval signatures on a protocol is a conflict of interest.

IACUC officials are the only approving authority for research activities.

Correct by October 21, 2002

Section 2.31(d) (4) IACUC review of activities involving animals. The IACUC shall notify principal investigators and the research facility in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval.

There is no written notification to the principle investigator nor the research facility citing approval of activities related to the care and use of animals.

Regulations require that investigators are notified in writing of approvals.

Correct by October 21, 2002

Prepared By:

Michael Smith
MICHAEL SMITH, USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER, Inspector ID: 5019

Received By:

Theresa Gadbois
THERESA GADBOIS

Title: IACUC CHAIR

Date:

OCT-03-2002

Date:

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